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10/583,029	05/10/2007	Toshihiro Takeda	AAO-0278	8844
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RADER FISHMAN & GRAUER PLLC			CHU, KAIYEU K	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,029	TAKEDA ET AL.	
	Examiner	Art Unit	
	KAIYEU CHU	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 May 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 15 June 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/15/2006, 05/27/2009, 07/16/2009, 09/18/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This office action has taken into consideration the preliminary amendment filed on 05/22/2007. Claims 1-12 are pending.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies have been placed of record in the file.

Information Disclosure Statement

2. The following foreign patent document included in the information disclosure statement filed on 06/15/2006 has not been considered because no English translation has been provided: JP-56-20467.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means," "comprises," and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The disclosure is objected to because of the following informalities: the term "introduction chamber 15" (page 6, line 16) should be corrected to - -introduction chamber 13- - to fix the typographic error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the cross-sectional area of an air passage" in lines 14 and 15 and the limitation "the cross-sectional area of the space of the housing" in lines 16-17. There is insufficient antecedent basis for these limitations in the claim.

Also, claims 1 and 7 each contain two instances of the limitation "a space," and thus the intended reference of each instance of the limitation and the relationship between each instance of the limitation in each claim is unclear.

Claims 2-6 and 8-12 are rejected due to their dependency on either claim 1 or claim 7.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3771

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-2 and 5 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spearman et al. (US Patent No. 7,331,342 B2).

Regarding claim 1, Fig. 3 of Spearman teaches a humidifying device for humidifying a gas, with the water vapor contained in air, comprising: a hollow fiber bundle (75) formed by bundling a plurality of hollow fibers permeable by water vapor (see column 7, lines 1-7), the hollow fibers being orientated in a direction of a predetermined axis; a housing having a space for accommodating the hollow fiber bundle therein, and having an introduction port (74) for the gas to be humidified, communicating to bores of the hollow fibers (see column 7, lines 16-19), a discharging port (73) for the gas to be humidified, communicating to the bores of the hollow fibers (see column 7, lines 19-23), an air inlet (71) communicating to a space in the housing external of the hollow fibers (see column 7, lines 23-25) to introduce atmospheric air (83) (see column 7, lines 34-36), and an air exit (72) communicating to the space in the housing external of the hollow fibers (see column 7, lines 23-25); and blowing means (40) arranged at the air inlet of the housing for introducing the atmospheric air into the housing (see Fig. 2; column 4, line 65 – column 5, line 4), wherein a ratio between a sum of the cross-sectional areas of the hollow fibers taken along a plane perpendicular to the axis, and the cross-sectional area of an air passage, is set within a range from 0.1 to 0.7, the cross-sectional area of the air passage being obtained by subtracting the sum of the cross-sectional areas of the hollow fibers from the cross-sectional area of the space of the housing taken along a plane perpendicular to the axis (although not

specifically addressed in the specification of Spearman, the ratio of cross-sectional areas based on Fig. 3 appears to be approximately 8/23, which is within the claimed range). Even if the ratio of cross-sectional areas in the air passage of Spearman is not 8/23, the feature of choosing a particular size of the hollow fibers and of the air passage to result in a ratio of cross-sectional areas of 8/23 is considered as an obvious design choice because it appears that Spearman's device would perform equally well with such a particular ratio.

Regarding claim 2, the ratio of cross-sectional areas based on Fig. 3 of Spearman appears to be approximately 8/23, which is within the claimed range of 0.2 to 0.6.

Regarding claim 5, Spearman teaches that the gas to be humidified is an oxygen-concentrated gas (see column 1, lines 12-16).

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Goel (US Publication No. 2004/0115489 A1).

Regarding claim 3, Spearman does not disclose that the hollow fiber is comprised of a polyimide membrane or a polyether-imide membrane. However, Goel teaches that hollow fibers may be formed from polyether-imides or polyimides membranes (see [0054], lines 1-4). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the fiber bundles of Spearman out of a polyimide membrane or a polyether-imide membrane as taught by Goel, as these membranes provide excellent water flux and selectivity for water over any

unwanted component, as well as remain stable after continuous long-term operation (see Goel: [0051], lines 1-12).

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Daniell et al. (US Patent No. 6,050,260).

Regarding claim 4, Spearman does not teach a humidity sensor provided at the discharging port for detecting the humidity of the gas to be humidified; and a control section for controlling the blowing means to make the humidity of the gas to be humidified, as detected by the humidity sensor, equal to a predetermined value. However, Fig. 1 Daniell teaches a humidity sensor (14) (see column 4, lines 17-19 and 21-24) provided at the discharging port for detecting the humidity of the gas to be humidified (see column 4, lines 6-19); and a control section (9) for controlling the blowing means (15) to make the humidity of the gas to be humidified, as detected by the humidity sensor, equal to a predetermined value (see column 3, line 66 – column 4, line 6; column 4, lines 25-37). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the oxygen humidifier of Spearman with a humidity sensor at its discharging port and a control section for controlling blowing means as taught by Daniell in order to improve the control the oxygen humidifier of Spearman has over humidification level as desired by the user.

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Izumi et al. (US Patent No. 4,453,952).

Regarding claim 6, Spearman teaches an oxygen concentrating system, the system adsorbing nitrogen contained in the air and removing it therefrom to produce an oxygen-concentrated gas for a medical use (see column 4, lines 16-18), and comprising: an oxygen concentrating section of a pressure-swing adsorption type (17, adsorption bed of molecular sieves) (see column 4, lines 14-32); a conduit for introducing the oxygen-concentrated gas produced in the oxygen concentrating section to a user (see column 5, lines 40-42; there must be a conduit in order to deliver the oxygen-enriched gas to the patient); pressure-adjustment means (54) disposed in the conduit for adjusting a pressure at an exit of the oxygen concentrating section to a constant value (see column 5, lines 34-37); flow rate regulating means (57) for regulating a flow rate of the oxygen-concentrated gas flowing through the conduit to a constant value (see column 5, lines 37-40). It is noted that Spearman does not disclose the oxygen concentrating section having a plurality of adsorption columns, the columns respectively accommodating adsorbents having a selective absorbability for nitrogen. However, Izumi teaches a plurality of adsorption columns (see column 6, lines 28-30) accommodating Na-A adsorbents (see column 5, lines 3-11) that may have a selective absorbability for nitrogen (see column 3, lines 18-23), and also that nitrogen-selective adsorbents such as the molecular sieves "5A" and "13X" are well-known for being employed in processes for the concentration of oxygen by removing nitrogen selectively from air (see column 1, lines 53-59). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the adsorption bed of Spearman to include adsorption columns with nitrogen-selective adsorbents as

taught by Izumi in order to provide an alternate way to adsorb nitrogen and produce an oxygen-rich gas.

14. Claims 7, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. (US Patent No. 6,582,955 B2).

Regarding claim 7, as the humidification device of Spearman contains only a single fiber bundle, Spearman does not teach that the humidification device comprises a plurality of fiber bundles. However, Martinez teaches a bioreactor using a plurality of hollow fiber bundles (see column 2, lines 60-65). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the humidification device of Spearman to use multiple hollow fiber bundles as taught by Martinez in order to more evenly humidify the dry gas passing through the hollow fibers.

Regarding claim 9, the modified humidification device of Spearman and Martinez does not specify that each of the hollow fiber bundles include 50 to 1000 hollow fibers. However, the optimal number of hollow fibers within a hollow fiber bundle largely depends on the application of the device and the size of the hollow fibers. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include 50 to 1000 hollow fibers in each of the hollow fiber bundles for design choice considerations.

Regarding claim 11, refer to the rejection of claim 5 for reasoning.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. as applied to claims 7,9, and 11 above, and further in view of Goel.

Regarding claim 8, the modified humidification device of Spearman and Martinez does not teach that the hollow fiber is comprised of a polyimide membrane or a polyether-imide membrane. However, Goel teaches that hollow fibers may be formed from polyether-imides or polyimides membranes (see [0054], lines 1-4). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the fiber bundles of the modified humidification device of Spearman and Martinez out of a polyimide membrane or a polyether-imide membrane as taught by Goel, as these membranes provide excellent water flux and selectivity for water over any unwanted component, as well as remain stable after continuous long-term operation (see Goel: [0051], lines 1-12).

16. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. in further view of Daniell et al.

Regarding claim 10, the modified humidification device of Spearman and Martinez does not teach a humidity sensor provided at the discharging port for detecting the humidity of the gas to be humidified; and a control section for controlling the blowing means to make the humidity of the gas to be humidified, as detected by the humidity sensor, equal to a predetermined value. However, Fig. 1 Daniell teaches a humidity sensor (14) (see column 4, lines 17-19 and 21-24) provided at the discharging port for

detecting the humidity of the gas to be humidified (see column 4, lines 6-19); and a control section (9) for controlling the blowing means (15) to make the humidity of the gas to be humidified, as detected by the humidity sensor, equal to a predetermined value (see column 3, line 66 – column 4, line 6; column 4, lines 25-37). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified humidification device of Spearman and Martinez with a humidity sensor at its discharging port and a control section for controlling blowing means as taught by Daniell in order to improve the control the modified humidification device of Spearman and Martinez has over humidification level as desired by the user.

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. in further view of Izumi et al.

Regarding claim 12, the modified humidification device of Spearman and Martinez teaches an oxygen concentrating system, the system adsorbing nitrogen contained in the air and removing it therefrom to produce an oxygen-concentrated gas for a medical use (Spearman: column 4, lines 16-18), and comprising: an oxygen concentrating section of a pressure-swing adsorption type (Spearman: 17, adsorption bed of molecular sieves) (Spearman: column 4, lines 14-32); a conduit for introducing the oxygen-concentrated gas produced in the oxygen concentrating section to a user (Spearman: column 5, lines 40-42; there must be a conduit in order to deliver the oxygen-enriched gas to the patient); pressure-adjustment means (Spearman: 54) disposed in the conduit for adjusting a pressure at an exit of the oxygen concentrating

section to a constant value (Spearman: column 5, lines 34-37); flow rate regulating means (Spearman: 57) for regulating a flow rate of the oxygen-concentrated gas flowing through the conduit to a constant value (Spearman: column 5, lines 37-40). It is noted that the modified humidification device of Spearman and Martinez does not disclose the oxygen concentrating section having a plurality of adsorption columns, the columns respectively accommodating adsorbents having a selective absorbability for nitrogen. However, Izumi teaches a plurality of adsorption columns (see column 6, lines 28-30) accommodating Na-A adsorbents (see column 5, lines 3-11) that may have a selective absorbability for nitrogen (see column 3, lines 18-23), and also that nitrogen-selective adsorbents such as the molecular sieves "5A" and "13X" are well-known for being employed in processes for the concentration of oxygen by removing nitrogen selectively from air (see column 1, lines 53-59). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the adsorption bed of the modified humidification device of Spearman and Martinez to include adsorption columns with nitrogen-selective adsorbents as taught by Izumi in order to provide an alternate way to adsorb nitrogen and produce an oxygen-rich gas.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. King et al. (US Patent No. 4,315,819) teaches a hollow fiber permeator apparatus with the packing factor of the hollow fibers in the permeator about 35 to 65 percent. Jackson (US Patent No. 4,381,267) teaches an airway humidifier that

uses water to surround the air transmitting hollow fibers and thus humidify the air.

Katagiri et al. (US Publication No. 2001/0015501 A1) teaches a humidifier consisting of a housing and water permeable hollow fiber membranes located within the housing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAIYEU CHU whose telephone number is (571)270-5376. The examiner can normally be reached on Monday-Friday 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. C./
Examiner, Art Unit 3771
02/18/2010

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771